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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,277	03/09/2006	Hideyuki Okano	09707.0009	6053

22852 7590 10/30/2009

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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
10/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,277	OKANO ET AL.	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *1-17,20,23-26 and 28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19,21,22,27 and 31-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07-13-2009 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-41 are currently pending. Claims 18, 21, 32 and 36 has been amended by Applicant's amendment filed on 07-13-2009. Claims 1-17, 20, 23-26 and 28-30 were previously withdrawn from consideration as being directed to non-elected inventions pursuant to 37 CFR1.14(b), there being no allowable generic or linking claim. Applicants' election of species Galectin-1 in the reply filed on 11-15-2007 was previously acknowledged.

Therefore, claims 18, 19, 21, 22, 27 and 31-41 are currently under examination to which the following grounds of rejection are applicable.

Response to arguments

Rejection maintained in response to Applicants' arguments or amendments.

Claim Rejections - 35 USC § 103

The specification as filed does not define the term "vicinity". As such, and in view of the customary and ordinary meaning of the term "vicinity " in the art as "the quality or state of being near" (Webster's Seventh New Collegiate Dictionary, G. C. Merriam Co.), the phrase "vicinity of the neuronal stem cells in the brain" is broadly but reasonably interpreted as administering

Galectin-1 to any region of the brain wherin neuronal stem cells are located. Moreover, the claimed methods embraced by independent claims 18, 21, 32 and 36 encompass solely one active step, i.e., administering Galecting-1 to the vicinity of the neuronal stem cells. However, the recitation of the intended used in claims 18, 21, 32 and 36, namely, proliferation of a neuronal stem cell in the preamble of claims 18 and 32 or proliferation of a SVZ astrocyte in claims 21 and 36 fails to impart any physical or structural property to the method of administration (e.g., wherein administration of the therapeutically effective amount of Galecting-1 increases proliferation of SVZ astrocytes or increases proliferation of neuronal stem cells). Neuronal stem cells are present in the brain. Accordingly, administering Galecting-1 to the vicinity of the neuronal stem cells implicitly would be expected to regulate processes associated with stem cell proliferation, stem cell differentiation, stem cell survival or any function associated with administration of Galecting-1 to the brain. Moreover, the specification does not define the term proliferation; hence the term can broadly but reasonably interpreted as one cell that replicates into two.

Claims 18, 19, 27 and 31- 35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Horie et al., (US Patent 6,890,531, Date of Issue May 10, 2005).

Horie et al., teaches a method for treating widely divergent neurological disorders including neurodegenerative diseases such as neuropathy and nerve injury resulting from ischemia (col. 2, lines 2-3; col. 13, lines 15-24). Note that treatment of cerebral ischemia and neural degenerative disease is embraced by claim 33 and 37 of the invention. Moreover, Horie et al., discloses treatment of nerve damage resulting from **central and peripheral** nerve injuries due to drugs, heavy metals, alcohols, ischemia or infection, malignancy or metabolic disorders

such as diabetic neuropathy, or dysfunction in kidney and others (col. 5, lines 16-26) comprising treatment of degenerating nerve tissue or apoptosis and promoting the regeneration of neurites (col. 3, lines 1-5). Horie et al., also teaches treatment of neuropathies of central nerves caused by nerve injuries e.g., ischemia, infection, malignant tumor or metabolic disorder or degeneration of specific nerve system cells e.g., amyotrophic lateral sclerosis, diabetic neuropathy, dementia senilis, Alzheimer's disease, Parkinson's disease (col. 2, lines 14-24; col. 13, lines 6-29), wherein administration of galectin-1, contained in collagen, for example, is directly imbedded into the neurological location for treatment (col. 11, lines 60-61). Additionally, Horie et al., teaches that administration of Galactin-1 can be done at the site of the nerve injury, or by oral and parenteral administration (col. 5, lines 29-30, 40-41) (Current claims 18, 19, 31-33 and 35). Though Horie et al., does not explicitly teach administration of Galactin-1 to the brain, administration of Galactin-1 at the site of the nerve injury implicitly requires administration to the brain as the nerve tissue, e.g., nerve cells or neurons, is present in the brain. Furthermore, Horie et al., discloses mutant Galactin-1 polypeptide wherein 6 cysteine residues are cross-bridged (oxidized) with a disulfide bond(s)(col. 4, lines 47-67) .Horie discloses mutant Galactin-1 polypeptide in which a cys at position 2 was converted to ser (col. 38, lines 35-38; col. 39, lines 15-19) (Current claims 27 and 34, in part).

Based on the teachings of Horie et al., of the treatment of cerebral ischemia and neural degenerative disease by administration of Galactin-1 to central nerve sites, one of ordinary skill in the art would recognize that treatment of cerebral ischemia and neural degenerative disease by administration of Galactin-1 implicitly involves regeneration and remyelinization from nerve injuries. Additionally, one of ordinary skill would recognize that proliferation of neuronal stem

cells, though no explicitly disclosed by Horie et al.,, would be intrinsically necessary to the administration of Galactin-1 to the brain wherein neuronal stem cell are located, (e.g., stem cell proliferation, stem cell differentiation, stem cell survival or any function associated with administration of Galecting-1 to the vicinity of the neuronal stem cells in the brain). Of note, the recitation of the intended used in the claimed invention, namely, proliferation of a neuronal stem cell in the preamble of claims 18 and 32 fails to impart any physical or structural property to the method of administration (e.g., wherein administration of the therapeutically effective amount of Galecting-1 increases proliferation of a neuronal stem cell). Thus proliferation of neuronal stem cells would reasonably be expected as the reference of Horie clearly discloses the same step of the claimed methods, i.e., administration of Galactin-1 to the brain in the vicinity of the neuronal stem cells. As neuronal stem cells are located in the brain, there would have been a reasonable expectation of success that administration of Galecting-1 for the treatment of cerebral ischemia and neural degenerative disease as taught by Horie implicitly would regulate brain processes associated with stem cell proliferation, stem cell differentiation, stem cell survival or any function associated with administration of Galecting-1 in the brain given the results the publication demonstrating the success of the methodology, and materials detailed in the disclosure.

Response to Applicants' Arguments as they apply to rejection of claims 18, 19, 27 and 31- 35 under 35 USC § 103

At pages 9, 10 and 11 of the remarks filed on 07-13-2009, Applicants essentially argue that: 1) the office should consider the entirety of the reference of Wells and not merely the fact that Well discloses that Galactin-1 is constitutively associated with cell growth and replication,

2) Wells discloses other significant differences that are not considered by the Office, 3) the MPEP instructs that obviousness cannot be predicted on what is not known at the time an invention was made, even if the inherency of a certain feature is later established, and 4) Horie does not teach administration of Galectin-1 to the vicinity of the neural stem cells in the brain and does not teach or suggest the same step method. The above arguments have been fully considered but deemed unpersuasive.

Regarding 1), 2) and 3), the fact that the MPEP instructs that obviousness cannot be predicted on what is not known at the time an invention was made, even if the inherency of a certain feature is later established is not disputed. However, as stated in the paragraphs above, the instant claims do not place any limitation on the resulting functionality of administering Galectin-1 to the vicinity of the neuronal stem cells. Since no such limitation exists in the claims as written, it is clear that administering Galectin-1 in the brain wherein neural stem cells inherently would induce proliferation of stem cells in the brain. As such Horie et al., by teaching treatment of neuropathies of central nerves in the brain by administration of galectin-1 for treatment would inherently obviate the instant claims. As set forth in the paragraphs above, the recitation of the intended used in the claimed invention fails to impart any physical or structural property to the method of administration

Regarding 4), as administration to the vicinity of the neuronal stem cells in the brain of the vertebrate is broadly interpreted as administration of Galectin-1 to the brain, Horie et al., teaches that galectin-1 is directly administrated to the central nerve sites which includes the brain, alternatively, galectin-1 is combined with a pharmaceutical carrier e.g., galectin-1 contained in collagen, to be directly imbedded into the neurological location for treatment (col.

5, lines 29-30, 40-41; col. 11, lines 60-61). Of note, the central nerve system includes the spinal cord level and brain level.

Claims 21, 22, 36 and 37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Horie et al., (US Patent 6,890,531, Date of Patent May 10, 2005) as applied to claims 18, 19, 27, 31-34 and 35 above, and further in view of Gage et al., US Patent No. 6,436,389 (Date of Issue August 20, 2002) or Taupin et al., (Neuron, 2000, pp. 385-397).

The teachings of Horie et al. are outlined in the paragraphs above. Horie et al. fails to teach *in vivo* proliferation of a subventricular region (SVZ) astrocyte.

However, at the time the invention was made, Gage et al., discloses methods for the treatment of neurodegenerative disorders including neural degenerative diseases and cerebral ischemia (e.g., focal ischemia, hypoxic-ischemic encephalopathy) (col. 20, lines 30-65; line 66) comprising stereotaxically injection into the rat hippocampus of genetically modified AHPs (adult hippocampus-derived neuronal progenitor cells) (col. 28, Example 5, lines 8-22). Moreover, Gage et al., uses the glial fibrillary acidic protein (GFAP), an astrocytic marker, to detect *in vivo* proliferation of embryonic rat primary hippocampal neural progenitor cells (e.g, the subgranular layer of the dentate gyrus (DG)) (col. 29, lines 9; col. 30, lines 1-5). Furthermore, Gage et al., teaches that intracerebral administration of FGF-2 has been shown to stimulate neurogenesis in the adult rat subventricular region of the brain (col. 1, line 50-53) wherein neurogenesis occurs throughout adulthood (col. 17; lines 57-59). Likewise, Taupin et al., exemplifies cell division in the neurogenic regions of the rat subgranular layer and SVZ after stereotaxically injection into the rat hippocampus of genetically modified AHPs The author

concludes that neuronal stem/progenitor cells are undergoing cell division in the SVZ (p. 391, col. 2).

Based on the combined teachings of Horie et al., of the treatment of cerebral ischemia and neural degenerative disease by administration of Galactin-1 to central nerve sites, and Gage and Taupin, of the subgranular layer and SVZ being active neurogenetic areas of the brain, one of ordinary skill in the art would recognize that treatment of cerebral ischemia and neural degenerative disease by administration of Galactin-1 implicitly involves regeneration and remyelinization from nerve injuries. Additionally, one of ordinary skill would recognize that proliferation of neuronal stem cells, though no explicitly disclosed by Horie et al.,, would be intrinsically necessary to the administration of Galactin-1 to the brain wherein neuronal stem cell are located, (e.g., stem cell proliferation, stem cell differentiation, stem cell survival or any function associated with administration of Galecting-1 to the vicinity of the neuronal stem cells in the brain. Additionally, it would have been *prima facie* obvious for one of skill in the art, as a matter of design of choice to administer Galactin-1 to any brain region associate with the contemplated treatment of a neurological disorders in order to ameliorate said disorder in a subject, particularly to stimulate neurogenesis the subventricular region of the brain because this region is a rich neurogenic area). Of note, the recitation of the intended used in the claimed invention, proliferation of a SVZ astrocyte in claims 21 and 36 fails to impart any physical or structural property to the method of administration (e.g., wherein administration of the therapeutically effective amount of Galecting-1 increases proliferation of a SVZ astrocyte). Thus proliferation of SVZ astrocytes would reasonably be expected as the reference of Horie clearly discloses the same step of the claimed methods, i.e., administration of Galactin-1 to the brain in

the vicinity of the neuronal stem cells. As neuronal stem cells are located in the brain, there would have been a reasonable expectation of success that administration of Galecting-1 for the treatment of cerebral ischemia and neural degenerative disease as taught by Horie implicitly would regulate brain processes associated with proliferation of a SVZ astrocyte in the brain given the result the combined publications demonstrating the success of the methodology, and materials detailed in the disclosures.

Response to Applicants' Arguments as they apply to rejection of claims 21, 22, 36 and 37 under 35 USC § 103

At pages 11-12, Applicants essentially argue that : 1) administration of Galecting-1, which is not discussed in either Gage or Taupin, would facilitate proliferation of a SVZ astrocyte in particular, 2) the office has admitted that Horie and Wells cannot be compared to each other and 3) Wells teaches away from "enhancing *in vivo* proliferation". The above arguments have been fully considered but deemed unpersuasive.

Regarding 1, 2) and 3), the only active method step in the claims is the step of administering Galectin-1 to the vicinity of the neural stem cells in the brain. As it is clear that central nerve sites include the brain level wherein neuronal stem cells are present, any administration of Galectin-1 for treatment of neuropathies of central nerves as taught by Horie inherently would be expected to regulate brain processes associated with stem cell proliferation, stem cell differentiation, stem cell survival or any function associated with administration of Galecting-1 to the brain. Hence, the structural limitations of the method step of Horie and the step in the claimed invention necessarily and inherently results in stem cell proliferation, stem

cell differentiation, stem cell survival, SVZ astrocyte proliferation or any function associated with administration of Galecting-1 to the brain wherein neuronal stem cells are present.

Claims 18, 21, 32, 36, 38, 39, 40 and 41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Horie et al., (US Patent 6,890,531, Date of Issue May 10, 2005) in view of Johansson et al., (1999, Experimental cell research pp. 733-736).

Response to Applicants' Arguments as they apply to rejection of claims 18, 21, 32, 36, 38, 39, 40 and 41 under 35 USC § 103

At pages 12, 13 and 14, Applicants essentially argue that:1) the methods of Horie and Wells are very different and not comparable, 2) Johansson merely discloses the establishment of a tissue culture from dissociated hippocampus and lateral ventricle wall samples of two patients and does not involve administration of Galectin-1 to the cells, 3) Neuronal stem cells are not known to be around the sciatic nerve used in Examples 18 and 19 taught by Horie, 4) Wells provides no suggestion or implication that Galectin-1 enhances cell proliferation, 5) Wells uses fibroblasts and does not disclose neuronal stem cells explicitly or implicitly, and 6) even if Well could teach that Galectin-1 stops proliferation of fibroblast in the brain, the teachings would be irrelevant to the instant invention.

Regarding 1) the fact that evaluation of results from the teachings and methods of Horie and Wells are very different is not disputed. Note that the Wells et al., reference is not necessary to obviate the claimed invention. Neuronal stem cells are located in the brain. Though Horie et al., does not explicitly teach administration of Galactin-1 to the brain, administration of Galactin-1 at the site of the nerve injury to central nerve sites implicitly requires administration to the

brain as the nerve tissue, e.g., nerve cells or neurons, is present in the brain. As it is clear that central nerve sites include the brain level wherein neuronal stem cells are located, any administration of Galectin-1 for treatment of neuropathies of central nerves as taught by Horie inherently would be expected to regulate brain processes associated with stem cell proliferation, stem cell differentiation, stem cell survival, SVZ astrocyte proliferation or any function associated with administration of Galecting-1 to the brain.

In response to 2), applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding 3), 4), 5) and 6), applicants' arguments are not persuasive as they rely on limitations, e.g.," Wells provides no suggestion or implication that Galectin-1 can enhance cell proliferation" "Applicants discovered that Galectin-1 can enhance proliferation of neuronal stem cells" , that are not present in the claims. The recitation of the intended used in claims 18, 21, 32 and 36, namely, proliferation of a neuronal stem cell in the preamble of claims 18 and 32 or proliferation of a SVZ astrocyte in claims 21 and 36 fails to impart any physical or structural property to the method of administration (e.g., wherein administration of the therapeutically effective amount of Galecting-1 increases proliferation of SVZ astrocytes or increases proliferation of neuronal stem cells).

New Grounds of Rejection

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 18, 19, 21, 22, 31, 32-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language

Independent claims 18, 21, 32 and 36 recite, "administering Galectin-1 to the vicinity of the neuronal stem cells". The phrase "vicinity of the neuronal stem cells" is a relative concept that requires a comparative reference as to define the location in the brain wherein neuronal stem cells are located and how distant the administration is to that site. The term "vicinity" is indefinite because the specification does not clearly redefine the term. The specification as filed discloses at paragraph [0047] of the published application that "the injection site may be anywhere as long as it is in the brain, but the vicinity of the neural stem cells, e.g., the lateral ventricle" and at paragraph [0085], "Tissues in the vicinity of the lateral ventricle in both hemispheres from the brain tip to the crossing of the ventricle on the left and right hemispheres were isolated". Classically, the subventricular zone of the forebrain (SVZ) has been considered the most neurogenic area and the richest source of neuronal stem cells (Galli et al., 2003, Cir Res. pp. 598-608). However, it is unclear how far or close is the claimed vicinity to the neuronal stem cells or where the location of said cells. Are the neuronal stem cells located all over the brain? How far can the close approximation go to neuronal stem cells, 4mm, 15mm? As such, the metes and bounds of the claims cannot be determined.

Moreover, claims 18, 21, 32 and 36 are incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. While all of the technical

details of a method need not to be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practice. The only disclosed step in claims 18, 21, 32 and 36 is the administration of Galectin-1 to the vicinity of the neuronal stem cells in the brain. It is not apparent as to under what structural or functional parameters administration of Galectin-1 to the vicinity of the neuronal stem cells is indicative or correlative to the preamble of the claims.

Additionally, claim 18 and 32 recite "a method for enhancing proliferation of a neuronal stem cell", and claims 21 and 36, "a method for enhancing in vivo proliferation of a SVZ astrocyte". The specification at paragraphs [0095] and [0099] discloses that injection of Galectin increases the percentage of proliferating SVZ astrocytes (B) on the hemisphere contralateral to the Galectin-1 injection and transit amplifying cells (TA cells) (e.g, a part of SVZ astrocytes function as stem cells). Hence it is unclear how administration of Galectin-1 enhances proliferation of merely one SVZ astrocyte or a solely TA cell. Is there only one SVZ astrocyte or TA cell sensitive to Galectin-1 in the brain? As such, the metes and bounds of the claims cannot be determined.

Claims 19, 22, 31, 33-35 and 37-41 are indefinite insofar as they depend from claims 18, 21, 32 or 36.

For the purpose of a compact prosecution the claims have been interpreted as administering Galectin-1 to the brain.

Conclusion

Claims 18, 19, 21, 22, 27 and 31-41 are not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maria Leavitt/

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